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Significance of QbD in design and development of coated liposomes for nose to brain delivery

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Nose to brain delivery is noninvasive, direct and more effective route of administration than other invasive treatments that comes with many pitfalls. In this study quality by design (QbD) and risk assessment (RA) strategy was used for development of novel optimized liposomes encapsulated with propyl gallate (PG) for nose to brain delivery. This risk focused research helps to define target product profile, critical quality and process parameters were also analysed. The application of QbD helped in the box behnken design-based liposome preparation by the novel direct pouring method (DPM). Compatibility studies (FTIR, DSC, XRPD, TGA) were performed for materials used and for lyophilized optimized formulations. The prepared optimized liposomal preparations were characterized (particle size, polydispersity index, and surface charge). The surface morphology was also evaluated to confirm the precision of the RA and critical parameters based on QbD prediction. The following study verify that in formulation of liposomes the RA startegy has significant importance. The developed optimized formulation via this novel approach results in maximum encapslation efficiency and minimum particle size. The implimentation of this novel QbD deisgn and models can assists in, to develop the rationalize liposomal formulation for nose to brain delivery.

References

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